

URIC ACID/GOUT

REAGENT STRIPS FOR URINALYSIS



INTENDED USE

Reagent Strips for the rapid determination of Uric acid in urine.

SUMMARY AND EXPLANATION OF THE TEST

Uric acid is a chemical created when the body breaks down substances called purines. Purines are found in some foods and drinks, such as liver, anchovies, mackerel, dried beans and peas, beer, and wine. Purines are also a part of normal body substances, such as DNA.

Most uric acid dissolves in blood and travels to the kidneys, where it passes out in urine. If your body produces too much uric acid or doesn't remove enough of it, you may get sick. A high level of uric acid in the body is called hyperuricemia. Hyperuricemia may be observed in renal dysfunction, gout, leukemia, polycythaemia, atherosclerosis, diabetes, hypothyroidism or in some genetic diseases. Decreased levels are present in patients with Wilson's disease, bronchogenic carcinoma, severe hepatocellular disease and Hodgkin's disease. This test checks to see how much uric acid you have in your urine. Urine uric acid results do not reflect blood uric acid results. However, if the urine uric acid results continue to show abnormal results, you need to perform additional tests to confirm a diagnosis.

Creatinine is a byproduct of muscle metabolism and creatinine excretion into the urine is usually constant. Creatinine measurement is used in the diagnosis and treatment of renal diseases, to monitor renal dialysis, and as a calculation basis for measuring other urine analytes. Though the concentration (or dilution) of urine varies throughout the day, the urinary creatinine level is relatively stable which allows its measurement to be used as a corrective factor in random/spot urine samples. When albumin and creatinine are measured simultaneously from a single-void / random urine sample, the Uric acid to creatinine ratio (UCR) can be determined

WARNING AND PRECAUTIONS

For in vitro diagnostic use only. For professional use only.

CHEMICAL PRINCIPLES OF PROCEDURE AND INGREDIENTS

Uric acid: Uric acid is converted by uricase into allantoin and hydrogen peroxides. The hydrogen peroxide initiates the coupling of 4-aminoantipyrine to MAOS to form the chromogen is proportional to the amount of hydrogen peroxide generated from uric acid.

Ingredients: Uricase 1.5 KU, POD 3KU

STORAGE AND HANDLING

Store in a cool, dry place at temperatures between 2°C – 25°C. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. When stored in the original container, the product is stable up to the expiry date printed on the label and (or) vial pouch. Do not remove desiccant from pouch. Do not touch test areas of urine reagent strips. Do not open container until ready to use.

Discolouration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, confirm that the product is within its expiration date and is reacting properly using known negative and positive control materials. Do not use after the expiry date.

SPECIMEN COLLECTION AND PREPARATION

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimen or controls (e.g., BIO-RAD Liquid Unassayed Multiquel Control).

Each laboratory should establish its own goals for adequate standards of performance. Each lab worker should ensure that it complies with government and local requirements. **The use of fresh morning urine is recommended.** Collect urine in a clean, dry container that allows complete immersion of all the fields on the test strip. Do not add preservatives. Test the specimen as soon as possible, with the sample well mixed but not centrifuged. If immediate testing is not possible, the sample should be stored in the refrigerator, but not frozen, and then brought to room temperature before used in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination.

TEST PROCEDURE

The procedure must be followed exactly to achieve reliable results.

1. Dip the strip into the urine up to the test area for no more than two seconds.
2. Draw the edge of the strip along the brim of the vessel to remove excess urine; at this time, don't make the test areas touched to the brim of the vessel. Turn the strip on its side and tap once on a piece of absorbent material to remove any remaining urine; Excessive urine on the strip may cause the interaction of chemicals between adjacent reagent pads, so that an incorrect result may occur.
3. Compare the colours of the reagent pads exactly after 120 seconds with the color chart on the label under good light. While comparing, keep the strip horizontally to prevent possible mixing of chemicals when excessive urine is present.

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THE LIMITATIONS OF TEST METHODS

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result of method. Substances that cause abnormal urine color may affect the readability of test pads in urinalysis reagent strips. **Uric acid:** Ascorbic acid concentrations (>30 mg/dl) may cause false negative at the high level of uric acid. **Note: The test result will not be accurate if Vitamin C is taken before bedtime or on a regular basis.**

EXPACTED VALUE

Result (mg/L)	100-300	700-1500
Interpretation	Normal	Abnormal

Elevated uric acid levels can be seen in the following;

- Gout
- Renal failure
- Lactic acidosis
- Hypothyroidism
- Sarcoidosis

Note: The number ranges are to be used only as a guide and a normal range of uric acid in urine may vary among different laboratories. Some laboratories will use different measurements and sample types. For example, blood maybe used to diagnose uric acid levels.

PERFORMANCE CHARACTERISTICS

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of colour perception; the persence or absence of inhibitory and matrix factors typically found in urine; and the laboratory conditions in which the product is used (e.g., lighting, temperature, and humidity). Each colour block represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between normal levels may give results at either level. Results will usually be within one level of the true concentration. The following list shows the generally detectable levels of the analytes in contrived urines; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions.

A comparison of results between the reference method (Cobas C501 System, Chemistry Analyzer, Roche diagnostics) and Uric acid strips revealed a good concordance of 83%. These results were obtained by using 155 samples at hospitals.

BIBLIOGRAPHY

-Levey AS, Coresh J, Balk E, et al. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification, stratification. Ann Intern Med. 139:137-147; 2003.

NOTES ON SYMBOLS

	Consult instructions for use
	In vitro diagnostic
	Use By /Expiry Date(YYYY-MM)
	Do not reuse
	Store at
	Keep away from sunlight
	Number of test strips
	EU Authorized Representative

References

J Rheumatology 2014 september 10, Spot urine uric acid to creatinine ratio used in the estimation of uric acid excretion in primary gout

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